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10/031,170	02/04/2002	Paul Douglas Clarke	TPP 31435	4789

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Stevens Davis Miller & Mosher
Suite 850
1615 L Street NW
Washington, DC 20036

EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/06/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/031,170

Applicant(s)

CLARKE, PAUL DOUGLAS

Examiner

Susan Coe

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 10-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-17, 20-23, 26-30, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 10-12, 18, 19, 24, 25 and 31-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other: .

DETAILED ACTION

1. The preliminary amendment filed February 4, 2002 has been received and entered.
2. Claims 1-5 and 9 have been cancelled.
3. Claims 26-35 have been added.
4. Claims 6-8 and 10-35 are currently pending.

Election/Restrictions

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 6-8, 10-12, 18, 19, 24, 25, and 31-33, drawn to a p-menthane-3,8-diol (PMD) composition.

Group II, claim(s) 13-17, 20-23, 26-30, 34, and 34, drawn to a method for sanitization.

6. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features as demonstrated by the fact that a reference that would anticipate claims drawn to the PMD composition would not necessarily anticipated the claims drawn to its method of use. For example, US Pat. No. 5,017,377 is considered to anticipate the composition claims but not the method claims. Therefore, the invention lacks unity.

During a telephone conversation with Mr. Thomas Pavelko on September 3, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 6-8, 10-12, 18, 19, 24, 25 and 31-33. Affirmation of this election must be made by applicant in replying to this Office action.

7. Claims 13-17, 20-23, 26-30, 34, and 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Claims 6-8, 10-12, 18, 19, 24, 25 and 31-33 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 31 is indefinite because it is not clear what characteristics the composition must possess in order to be considered a "crude" product.

10. Claim 32 is indefinite because it is not clear how much PMD must be in the extract composition in order for the composition to be considered a "PMD-rich extract." Also it is unclear what limitations must be met in order for the PMD to be considered "natural."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 6, 7, 18, 19, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,017,377.

Applicant's claims are drawn to a composition comprising PMD (p-menthane-3,8-diol).

US '377 discloses PMD that can be impregnated in a plastic. The PMD is a mixture of isomers (see claims). The PMD can also contain an oil (see column 6, lines 36-49).

The reference does not specifically teach that the composition has the same effects as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

12. Claims 6-8, 10-12, 18, 24, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,298,250.

US '250 teaches a PMD composition. The composition can be in the forms of PMD isomers (see claims). The PMD can be a lotion or an aerosol with water and alcohols (see column 10, lines 36-48). The reference also teaches the PMD is in extracts from Eucalyptus citriodora (lemon eucalyptus) (see column 1, lines 40-46).

The reference does not specifically teach that the composition has the same effects as those claimed by applicant; however, since the composition taught by the reference is the same

Art Unit: 1651

as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

13. Claims 6-8, 10-12, 18-19, 24, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,698,209.

US '209 teaches a PMD composition. A mixture of PMD isomers can be used (see column 1, lines 51-53). The PMD composition can contain numerous carriers and can be in the form of an aerosol, lotion, liquid, or cream (see column 2). The PMD composition can also be impregnated on plastics or fabrics (see column 3, lines 13-22).

The reference does not specifically teach that the composition has the same effects as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

14. Claims 6-8, 10-12, 18, 24, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Shahi et al. (Current Science (Bangalore) (March 1999), vol. 76, no. 6, pp. 836-839).

Shahi teaches a lemon eucalyptus oil that has antifungal properties. The oil is administered as an ointment (see page 837, last paragraph). Shahi does not specifically teach that the oil contains PMD. However, PMD would be present in the lemon eucalyptus oil; therefore, the oil taught by Shahi is considered to be a composition that contains PMD.

15. Claims 6, 7, 18, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Muanza et al. (Int. J. Pharmacog (1994), vol. 32, no. 4, pp. 337-345).

Maunza teaches a lemon eucalyptus extract that has antifungal and antibacterial properties (see page 341). Maunza does not specifically teach that the extract contains PMD. However, PMD would be present in the lemon eucalyptus extract; therefore, the extract taught by Maunza is considered to be a composition that contains PMD.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 6-8, 10-12, 18, 19, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,017,337.

As stated above, the reference is considered to teach the claimed composition; however, the reference does not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

17. Claims 6-8, 10-12, 18, 19, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No 5,298,250.

As stated above, the reference is considered to teach the claimed composition; however, the reference does not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

18. Claims 6-8, 10-12, 18, 19, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,698,209.

As stated above, the reference is considered to teach the claimed composition; however, the reference does not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

19. Claims 6-8, 10-12, 18, 19, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahi et al. (Current Science (Bangalore) (March 1999), vol. 76, no. 6, pp. 836-839).

Art Unit: 1651

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20. Claims 6-8, 10-12, 18, 19, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muanza et al. (Int. J. Pharmacog (1994), vol. 32, no. 4, pp. 337-345).

As stated above, the reference is considered to teach the claimed composition; however, the reference does not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

21. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The

Art Unit: 1651


examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC

September 3, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER